REMARKS

In the Office Action, Claims 2-5, 7 and 8 are rejected under 35 U.S.C. §103; Claim 6 has been objected; and Claims 32-33 have been allowed. Claim 34 has been newly added. Applicants believe that the rejections have been overcome or are improper in view of the amendments and/or for the reasons set forth below.

At the outset, Claims 32 and 33 have been allowed as previously discussed. Further, Claim 6 has been objected to because of its dependence on a rejected claim, namely, independent Claim 2. As previously discussed, Claim 34 has been newly added. Claim 34 essentially includes the limitations of independent Claim 2 in addition to Claim 6. Claim 6 has also been canceled without prejudice or disclaimer. Thus, newly added Claim 34 should be allowed as well.

In the Office Action, Claims 2-5, 7 and 8 rejected under 35 U.S.C. § 103. More specifically, Claims 2-5, 7 and 8 are rejected as being unpatentable over U.S. Patent No. 4,880,629 ("*Okamoto*") in view of U.S. Patent No. 5,039,609 ("*Klein*"); Claims 2-3 are rejected as being unpatentable over *Okamoto*, *Klein* and further in view of U.S. Patent No. 4,997,083 ("*Loretti*") or U.S. Patent No. 4,608,043 ("*Larkin*"); Claims 2-5, 7 and 8 are rejected as being unpatentable in view of *Klein* and U.S. Patent No. 5,092,838 ("*Faict*"); Claims 2-3 are rejected as being unpatentable in view of *Klein* and *Faict* and further in view of *Loretti* or *Larkin*; and Claims 2-5, 7 and 8 are rejected as being unpatentable in view of *Klein* and U.S. Patent No. 5,011,826 ("*Steudle*").

Applicants believe that the obviousness rejections are improper. In general, the present invention provides an improved dialysis solution. The improved dialysis solution provides for the use of specific polypeptides as an osmotic agent with an additional osmotic agent, such as dextrose. The inventors have found that selecting well-defined polypeptides and utilizing same with an additional osmotic agent can overcome the disadvantages of using polypeptides alone or dextrose alone set forth on pages 10-26 of the Specification.

Of the rejected claims, Claim 2 is the sole independent claim. Claim 2 recites a two part peritoneal dialysis solution designed to be mixed prior to infusion into a patient. The two part peritoneal dialysis solution includes, in part, a first part housed in a first structure and a second part housed in a second structure. The first part includes approximately 1.0 to about 8% (w/v)

dextrose and a pH of approximately 4.0 to about 5.5; and the second part includes approximately 0.5 to about 8.0% (w/v) polypeptides and a pH of approximately 6.0 to about 7.5.

In contrast, Applicants believe that the cited art, even if combinable, fails to disclose or suggest at least a number of features of the claimed invention. At the outset, Applicants believe that the claim term "designed to be mixed prior to infusion into a patient" provides "life, meaning, and vitality" to the claimed subject matter and thus, should be given patentable weight contrary to the Patent Office's position. Indeed, where the preamble has been clearly relied on during prosecution to distinguish over the cited art and where the Specification supports this position, the preamble should be given patentable weight as a matter of law.

To date, Applicants have, and continue to argue that the two part peritoneal dialysis solution of the claimed invention includes a dextrose-based part and a polypeptide-based part that are mixed prior to infusion into a patient during peritoneal dialysis, and that the two part solution as claimed is clearly patentable over the purported solutions disclosed in the cited art. As further supported in the Specification on page 8, an advantage of the present invention is to provide a balanced supplementation of polypeptides and dextrose through a dialysis solution to improve the nutritional status of a renal patient. In view of same, Applicants believe that the preamble language at issue would give guidance and understanding to one skilled in the art in ascertaining the scope and meaning of the claimed invention. Therefore, Applicants believe that the Examiner's position regarding same is inappropriate and thus respectfully request reconsideration of same.

In any event, Applicants believe that the cited art, even if combinable, is clearly deficient with respect to the claimed invention. For example, nowhere does the *Klein* reference disclose or suggest adding polypeptides and dextrose in solution to form a peritoneal dialysis solution, let alone the specific amounts of polypeptides and dextrose as required by the claimed invention. Indeed, the Patent Office's apparent attempt to suggest that *Klein* discloses dextrose in addition to peptides in solution is incorrect and a mischaracterization of *Klein*.

In column 12, beginning at line 39, *Klein* merely suggests that a concentration of electrolytes can be added to facilitate the osmotic properties of the solution. For example, *Klein* discloses that a typical solution can contain specific quantities of sodium, chloride, lactate, magnesium and calcium. See, *Klein*, column 12, lines 48-51, Table 2. However, nowhere does

Klein suggest in this passage as the Patent Office seems to assert that glucose/dextrose can be added to the peptide solution. To the contrary, this passage merely suggests that a glucose solution typically contains a glucose monohydrate in an amount from about 1.5 to 4.25%. Again, the clear emphasis of *Klein* relates to osmotically active agents used in peritoneal dialysis solutions that substitute polypeptides for dextrose. This is clearly suggested in *Klein*. For example, Example 4 compares the purported effectiveness of a peptide solution to a glucose solution. Moreover, Applicants believe that the experimental tests (e.g., Examples 1 and 2) disclosed in Applicants' Specification are relevant and further demonstrate the advantages of the claimed invention over *Klein*. Based on at least these reasons, Applicants believe that *Klein* is clearly deficient with respect to the claimed invention.

Even if combinable, the other cited art does not appear to remedy the deficiencies of *Klein*. In this regard, the Patent Office primarily relies on the other cited art for their alleged and general teachings regarding peritoneal dialysis solutions that include glucose. For example, *Okamoto* merely relates to dialytic solutions that contain glycerol and monosaccharides as osmotic pressure regulating agents for regulating the osmotic pressure necessary for the removal of water. See, *Okamoto*, col. 5, lines 15-20.

With respect to the alleged teaching of *Steudle*, Applicants respectfully submit that the mere mention of a combination of peptide with glucose in the same sentence is not sufficient grounds for an obviousness rejection contrary to the Examiner's position. See, *Steudle*, col. 4, lines 51-59. Moreover, *Steudle* does not remedy the deficiencies of *Klein* with respect to the polypeptide features of the claimed invention. *Steudle* does not even provide any description of peptides that can be used as osmotic agents.

Indeed, *Steudle* does not define the circumstances wherein one would mix peptides with an osmotic agent, such as dextrose as required by the claimed invention. Instead, *Steudle* merely relates to the use of galactose as an osmotic active substance. In attempting to provide as broad a disclosure as possible, the *Steudle* patent makes a backhanded reference to peptides in column 4, line 58, along with an exhaustive list of the groups of possible osmotic agents to be used in addition to galactose and glucose.

With respect to the remaining references, the Patent Office primarily relies on *Faict* for its alleged teaching regarding a two part dialysis mixture that contains glucose in one part, and

histidine, or oligomers thereof, in another. Further, the Patent Officer merely relies on *Loretti* and *Larkin* for their alleged teachings regarding sterile containers which include two different chambers for mixing solutions. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify *Klein* in view of any hypothetical combination of the remaining cited art to arrive at the claimed invention.

At best, the cited art, even if combinable, simply provides "general guidance" as to the particular form of the claimed invention. Absent a suggestion, teaching or motivation of the specific compositions of the two part peritoneal dialysis solutions including polypeptides and dextrose claimed in the present invention, Applicants respectfully submit that the Patent Office has impermissibly applied hindsight reasoning in support of the prior art rejections.

Based on at least these noted differences between the cited art and the claimed invention, Applicants believe that the cited art fails to disclose or suggest at least a number of features of the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to the claimed invention be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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